

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
AND THE  
APPLICATION REVIEW SUBCOMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: FEBRUARY 22, 2018  
9 A.M.

REPORTER: BETH C. DRAIN, CSR  
CA CSR. NO. 7152

FILE NO.: 2018-05

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I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO PRE-CLINICAL AND CLINICAL TRIAL STAGE PROJECTS.	4
•CLIN1-10893 PUBLIC SUMMARY	10
•CLIN2-10847 PUBLIC SUMMARY	5
CLOSED SESSION	NONE
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO PRE-CLINICAL AND CLINICAL TRIAL STAGE PROJECTS (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
OPEN SESSION	
5. PUBLIC COMMENT.	NONE
6. ADJOURNMENT	18

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FEBRUARY 22, 2018; 9 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.  
WELCOME TO THE FEBRUARY REGULAR MEETING OF THE ICOC  
AND APPLICATION REVIEW SUBCOMMITTEE. MARIA, WILL  
YOU PLEASE CALL THE ROLL?

MS. BONNEVILLE: ANNE-MARIE DULIEGE.  
DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. DAVE  
MARTIN.

DR. MARTIN: HERE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT.

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MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

SUPERVISOR SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: DIANE WINOKUR.

CHAIRMAN THOMAS: THANK YOU, EVERYBODY.

WE'RE GOING TO ITEM NO. 3 --

DR. MALKAS: LINDA MALKAS IS HERE.

MS. BONNEVILLE: THANK YOU, LINDA.

CHAIRMAN THOMAS: ITEM NO. 3,  
CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE  
TO THE PRECLINICAL AND CLINICAL TRIAL STAGE  
PROJECTS. TURN THE MEETING OVER TO SUPERVISOR  
SHEEHY.

SUPERVISOR SHEEHY: THANK YOU, CHAIRMAN  
THOMAS.

DR. SAMBRANO, DO YOU HAVE A PRESENTATION  
TO START US OFF WITH?

DR. SAMBRANO: YES, I DO. THANK YOU,  
MR. SHEEHY. I'LL ALSO NOTE THAT I HAVE NEXT TO ME

1 DR. SEAN PATEL FROM THE REVIEW TEAM TO HELP ANSWER  
2 ANY QUESTIONS AS THEY COME UP.

3 SO I'M GOING TO TAKE YOU THROUGH THE  
4 PRESENTATION THAT'S AVAILABLE ON WEBEX AND THAT WAS  
5 DISTRIBUTED TO YOU. I'M STARTING OFF WITH JUST A  
6 REMINDER OF OUR PROGRAM. WE HAVE THREE PROGRAM  
7 ANNOUNCEMENTS THAT DESCRIBE THE CLINICAL PROGRAM.  
8 WE HAVE TWO APPLICATIONS, ONE THAT RESPONDS TO THE  
9 CLIN1 OPPORTUNITY FOR LATE-STAGE PRECLINICAL  
10 PROJECTS AND ONE APPLICATION FOR CLIN2 FOR CLINICAL  
11 TRIAL STAGE PROJECTS.

12 THE SCORING SYSTEM, AGAIN A REMINDER FOR  
13 HOW WE SCORE CLINICAL APPLICATIONS, IS SCORED ON A  
14 BASIS OF 1, 2, OR 3, WITH THE 1 BEING EXCEPTIONAL  
15 MERIT AND WARRANTING FUNDING, A SCORE OF 2 MEANING  
16 THAT IT NEEDS IMPROVEMENT AND IT CAN BE RESUBMITTED  
17 TO ADDRESS THOSE AREAS, AND THEN A SCORE OF 3 WHICH  
18 MEANS THAT IT'S SUFFICIENTLY FLAWED THAT IT WOULDN'T  
19 WARRANT FUNDING AND THOSE APPLICANTS CANNOT REAPPLY  
20 FOR SIX MONTHS.

21 SO THE FIRST APPLICATION TO BE CONSIDERED  
22 IS CLIN2-10847. THIS IS FOR A PHASE 1 CLINICAL  
23 TRIAL FOR A THERAPY BEING DEVELOPED FOR SICKLE CELL  
24 DISEASE. THE THERAPY IS A HAPLOIDENTICAL OR  
25 HALF-MATCH BLOOD STEM CELL TRANSPLANT WHERE THIS

1 PRODUCT IS DEPLETED OF CD4 POSITIVE T-CELLS. THE  
2 INDICATION IS FOR ADULT PATIENTS THAT HAVE SEVERE  
3 SICKLE CELL DISEASE AND THAT OTHERWISE DO NOT  
4 QUALIFY FOR THE STANDARD STEM CELL TRANSPLANT THAT  
5 IS AVAILABLE TO PATIENTS WITH SICKLE CELL DISEASE.

6 THE GOAL OF THIS STUDY IS TO COMPLETE A  
7 PHASE 1 CLINICAL TRIAL AND ASSESS THE SAFETY AND  
8 FEASIBILITY OF ACHIEVING MIXED CHIMERISM AND  
9 TOLERANCE. AND THE MIXED CHIMERISM MEANING THAT THE  
10 PATIENTS HAVE BOTH DONOR AND HOST BLOOD CELLS IN  
11 THEIR SYSTEM IN ORDER TO ACHIEVE TOLERANCE AND  
12 PREVENT SIDE EFFECTS SUCH AS GRAFT VERSUS HOST  
13 DISEASE.

14 THE FUNDS BEING REQUESTED BY THE APPLICANT  
15 IS APPROXIMATELY 5.7 MILLION. THE GWG  
16 RECOMMENDATION WAS THAT THIS IS A TIER I PROPOSAL  
17 WITH EXCEPTIONAL MERIT. THERE WERE SEVEN GWG VOTES  
18 THAT GAVE THIS A SCORE OF 1, FIVE THAT GAVE IT A  
19 SCORE OF 2, AND NONE A SCORE OF 3. THE CIRM TEAM  
20 RECOMMENDATION IS THAT WE CONCUR WITH THE GWG  
21 RECOMMENDATION TO FUND THIS PROJECT IN THE AWARD  
22 AMOUNT OF 5.7 MILLION.

23 MR. SHEEHY.

24 SUPERVISOR SHEEHY: GREAT. SO DO I HAVE A  
25 MOTION TO EITHER ACCEPT OR REJECT THE TEAM

1 RECOMMENDATION?

2 DR. MARTIN: MOVE TO ACCEPT.

3 DR. JUELSGAARD: SECOND.

4 SUPERVISOR SHEEHY: DO I HAVE A SECOND?  
5 STEVE?

6 DR. JUELSGAARD: SECOND.

7 SUPERVISOR SHEEHY: OKAY. DO WE HAVE  
8 BOARD DISCUSSION?

9 DR. STEWARD: YES. THIS IS OS STEWARD.  
10 COULD I ASK A QUESTION?

11 SUPERVISOR SHEEHY: PLEASE.

12 DR. STEWARD: SO IF ONE OF THE GWG MEMBERS  
13 VOTED DIFFERENTLY, THIS WOULD BE A TIE VOTE. AND MY  
14 QUESTION IS IF YOU COULD QUICKLY SUMMARIZE THE  
15 CONCERNS THAT WERE EXPRESSED BY THOSE WHO VOTED TIER  
16 II JUST TO GIVE US SOME PERSPECTIVE ON THIS  
17 RECOMMENDATION. THANK YOU.

18 SUPERVISOR SHEEHY: EITHER DR. PATEL OR  
19 DR. SAMBRANO.

20 DR. SAMBRANO: YES. I CAN HIGHLIGHT THEM  
21 AS THE CONCERNS THAT WERE BROUGHT UP BY THE GWG  
22 MEMBERS. SO THERE WERE CONCERNS THAT WERE  
23 RELATIVELY MINOR. SO THOSE THAT GAVE IT A SCORE OF  
24 2 WOULD HAVE LIKED MORE INFORMATION FROM THE  
25 APPLICANT OR TO SEE ADDITIONAL DATA AS IT RELATES TO

1 LARGE ANIMAL MODELS PROVIDING STRONGER SUPPORT FOR  
2 THEIR RATIONALE. MOST OF THE PRECLINICAL STUDIES  
3 WERE DONE IN A MOUSE MODEL. SO THEY WOULD HAVE  
4 LIKED TO HAVE SEEN ADDITIONAL DATA ON THAT.

5 THERE WAS SOME DISCUSSION OF REVIEWERS  
6 ABOUT THE SAMPLE SIZE IN TERMS OF WHETHER THAT  
7 SAMPLE SIZE WOULD BE SUFFICIENT TO INFORM FULLY ON  
8 SAFETY AND THE FEASIBILITY OF THE APPROACH. SOME  
9 FELT THAT IT WAS ADEQUATE AND IT WAS A GOOD WAY TO  
10 START THIS PROGRAM. OTHERS FELT THAT A LARGER  
11 SAMPLE SIZE MIGHT BE NECESSARY AS THEY MOVE ALONG  
12 THROUGH THIS.

13 ANOTHER AREA OF DISAGREEMENT, I THINK THIS  
14 WAS ALSO RELATIVELY MINOR, WAS WITH THE NOVELTY OF  
15 THE PRODUCT. SOME WERE LOOKING AT IT FROM THE  
16 PERSPECTIVE OF A STEM CELL THERAPY AND HOW THIS  
17 MIGHT ADVANCE STEM CELL THERAPY IN GENERAL. THEY  
18 FELT THAT THIS WAS A STANDARD METHOD BY WHICH -- A  
19 STANDARD STEM CELL TRANSPLANT. THERE WAS NOTHING  
20 NEW ABOUT HOW IT WAS BEING DONE. ON THE OTHER HAND,  
21 THE OVERALL APPROACH AND THE APPLICATION OF THE  
22 TRANSPLANT TO SICKLE CELL DISEASE IS NOVEL. AND SO  
23 I THINK THEY WERE CAPTURING TWO DIFFERENT ASPECTS OF  
24 THE GOALS OF THIS PROJECT. ON THE ONE HAND, ONE  
25 ASPECT OF IT NOT BEING SO NOVEL. ON THE OTHER HAND,

1 THE APPROACH BEING NOVEL.  
2 SO THOSE ARE KIND OF JUST THE BIG PICTURE  
3 OVERVIEW AREAS OF CONCERN.  
4 DR. STEWARD: THANK YOU.  
5 MS. WINOKUR: THIS IS DIANE.  
6 MS. BONNEVILLE: HI, DIANE. THANK YOU.  
7 SUPERVISOR SHEEHY: SO DO WE HAVE OTHER  
8 QUESTIONS, COMMENTS FROM BOARD MEMBERS? DO WE HAVE  
9 ANY PUBLIC COMMENT AT ANY OF THE SITES? OKAY.  
10 MS. BONNEVILLE, COULD YOU CALL THE ROLL PLEASE?  
11 MS. BONNEVILLE: ANNE-MARIE DULIEGE.  
12 DAVID HIGGINS.  
13 DR. HIGGINS: YES.  
14 MS. BONNEVILLE: STEVE JUELSGAARD.  
15 DR. JUELSGAARD: YES.  
16 MS. BONNEVILLE: SHERRY LANSING. DAVE  
17 MARTIN.  
18 DR. MARTIN: YES.  
19 MS. BONNEVILLE: LAUREN MILLER.  
20 MS. MILLER: YES.  
21 MS. BONNEVILLE: ADRIANA PADILLA.  
22 DR. PADILLA: YES.  
23 MS. BONNEVILLE: JOE PANETTA.  
24 MR. PANETTA: YES.  
25 MS. BONNEVILLE: FRANCISCO PRIETO.

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DR. PRIETO: AYE.  
MS. BONNEVILLE: ROBERT QUINT.  
DR. QUINT: YES.  
MS. BONNEVILLE: AL ROWLETT.  
MR. ROWLETT: YES.  
MS. BONNEVILLE: JEFF SHEEHY.  
SUPERVISOR SHEEHY: YES.  
MS. BONNEVILLE: OS STEWARD.  
DR. STEWARD: YES.  
MS. BONNEVILLE: JONATHAN THOMAS.  
CHAIRMAN THOMAS: YES.  
MS. BONNEVILLE: ART TORRES.  
MR. TORRES: AYE.  
MS. BONNEVILLE: DIANE WINOKUR.  
MOTION CARRIES.  
SUPERVISOR SHEEHY: THANK YOU,  
MS. BONNEVILLE.  
SO, DR. SAMBRANO, DO YOU HAVE THE SECOND  
APPLICATION?  
DR. SAMBRANO: YES. SO THE SECOND  
APPLICATION IS CLIN1-10893. THIS IS A PRECLINICAL  
STUDY OF NATURAL KILLER CELL IMMUNOTHERAPY FOR  
CANCER.  
SO THE THERAPY IS A NATURAL KILLER CELL  
PRODUCT THAT'S DERIVED FROM INDUCED PLURIPOTENT STEM

1 CELLS. THESE CELLS ARE TWEAKED, IF YOU WILL, TO  
2 MAKE THEM MORE EFFECTIVE IN TARGETING THE TUMORS AS  
3 WELL AS MORE RESISTANT TO THE MICROENVIRONMENT IN  
4 THE TUMOR THAT CAN SOMETIMES DEACTIVATE THOSE CELLS.

5 THE INDICATION IS FOR PATIENTS WITH  
6 ADVANCED CANCERS STARTING WITH THE INITIAL STUDY  
7 THAT WOULD TARGET BREAST, GASTRIC, COLORECTAL, OR  
8 HEAD AND NECK CANCERS. THE GOAL OF THIS STUDY IS TO  
9 DO PRE-IND ENABLING STUDIES AND THE MANUFACTURING  
10 PROCESSES FOR THE IND SUBMISSION IN ABOUT 18 MONTHS.

11 THE FUNDS THAT ARE REQUESTED BY THE  
12 APPLICANT IS 5.6 MILLION. I WILL NOTE THAT THE  
13 MAXIMUM FUNDS ALLOWABLE FOR THIS CATEGORY UNDER OUR  
14 NEW CAPS IS FOUR MILLION. SO WE HAVE DISCUSSED THIS  
15 WITH THE APPLICANT, AND THE APPLICANT HAS PROVIDED  
16 US WITH A LETTER THAT CONFIRMS THAT THEY ARE ABLE TO  
17 ACCEPT AN AWARD FOR FOUR MILLION AND PROVIDE THE  
18 DIFFERENCE IN THE CO-FUNDING AMOUNT. SO THEY WOULD  
19 PROVIDE THE 1.9 CO-FUNDING PLUS THE DIFFERENCE  
20 BETWEEN WHAT THE ORIGINAL REQUEST IS AND THE \$4  
21 MILLION.

22 SO THE GWG RECOMMENDATION ON THIS  
23 APPLICATION IS A TIER I, EXCEPTIONAL MERIT AND  
24 WARRANTS FUNDING. THERE WERE SEVEN VOTES, AGAIN, AS  
25 IN THE PREVIOUS, THAT GAVE THIS A SCORE OF 1, AND

1 FIVE THAT GAVE THIS A SCORE OF 2, AND NONE A SCORE  
2 OF 3. THE CIRM TEAM ALSO RECOMMENDS THIS  
3 APPLICATION FOR FUNDING WITH THE REDUCTION IN  
4 FUNDING AS PREVIOUSLY NOTED FOR AN AWARD AMOUNT OF  
5 \$4 MILLION.

6 MR. SHEEHY.

7 SUPERVISOR SHEEHY: THANK YOU, DR.  
8 SAMBRANO. COULD I HAVE A MOTION TO EITHER ACCEPT OR  
9 REJECT THE TEAM RECOMMENDATION?

10 DR. MARTIN: I'LL MOVE THE MOTION TO  
11 APPROVE. DAVE MARTIN.

12 SUPERVISOR SHEEHY: OKAY. DO WE HAVE A  
13 SECOND?

14 DR. JUELSGAARD: SECOND.

15 SUPERVISOR SHEEHY: ANY BOARD DISCUSSION?

16 DR. STEWARD: YES. THIS IS OS AGAIN. AND  
17 I'D LIKE TO ASK THE SAME QUESTIONS FOR EXACTLY THE  
18 SAME REASON. THANK YOU.

19 DR. SAMBRANO: OKAY. I'LL SUMMARIZE  
20 BRIEFLY AGAIN SOME OF THE CONCERNS THAT WERE RAISED  
21 BY SOME OF THE REVIEWERS.

22 SO SOME REVIEWERS WEREN'T CONVINCED FULLY  
23 ABOUT THE ADVANTAGE OF THE NK CELL AND ANTIBODY  
24 THERAPY OVER THE ANTIBODY MONOTHERAPY ALONE. SO  
25 WHAT THEY WERE LOOKING FOR WAS JUST PERHAPS

1 ADDITIONAL ANIMAL STUDIES OR A LARGER N IN THOSE  
2 STUDIES THAT DISTINGUISH THE COMBINED NK CELL  
3 THERAPY ALONG WITH THE ANTIBODY TO DEMONSTRATE THAT  
4 THERE IS ADDITIONAL EFFICACY THAT THE NK CELLS BRING  
5 TO THE TABLE.

6 THEY ALSO FELT THAT IT WAS IMPORTANT TO  
7 REASSESS THE PATIENTS WHO ARE GOING TO BE TARGETED  
8 FOR THIS IN TERMS OF WHETHER THEY STILL EXPRESS THE  
9 ANTIBODY TARGET JUST TO MAKE SURE THAT IF THEY ARE  
10 GOING TO BRING THESE PATIENTS IN, THAT THAT IS  
11 ASSESSED.

12 THERE WAS SOME CONCERN ABOUT WHETHER THE  
13 NK CELLS WOULD PERSIST. AND RELATED TO THAT,  
14 WHETHER THE PATIENTS WHO WOULD BE TYPED FOR HLA IN  
15 ORDER TO ASSESS WHETHER THAT MAY MAKE A DIFFERENCE  
16 IN TERMS OF (INAUDIBLE) AGAINST THESE CELLS OR EVEN  
17 JUST MONITOR THE REJECTION THAT MAY OCCUR. SO THOSE  
18 WERE SOME CONCERNS. AGAIN, I THINK THEY WERE  
19 LOOKING TO SEE IF THE APPLICANT MIGHT BE ABLE TO  
20 PROVIDE ADDITIONAL DATA ON THAT FOR THOSE THAT GAVE  
21 THIS A SCORE OF 2.

22 DR. STEWARD: THANK YOU, GIL. THIS IS OS.  
23 COULD I MAKE A COMMENT?

24 SUPERVISOR SHEEHY: SURE. PLEASE.

25 DR. STEWARD: SO MY FEELING ABOUT THIS ONE

1 IS A LITTLE BIT DIFFERENT IN THE SENSE THAT THE  
2 REQUEST FOR ADDITIONAL DATA COULD BE FULFILLED, I  
3 THINK, A LITTLE BIT MORE QUICKLY ON A FAST TIMELINE.  
4 AND I DON'T WANT TO DRAW COMPARISONS, SO I WON'T.  
5 BUT SOME OF THESE QUESTIONS, I THINK, ARE REALLY  
6 MAKE OR BREAK FOR THE PROJECT. AND IN PARTICULAR  
7 THE COMPARISON WITH OTHER POTENTIAL THERAPIES IS AN  
8 IMPORTANT ONE IN TERMS OF THE POTENTIAL MARKET SHARE  
9 GOING FORWARD.

10 SO, GIL -- OR MAYBE I'LL JUST LEAVE IT AT  
11 THAT AND SEE IF OTHERS HAVE ANY COMMENTS ON THAT.  
12 IF, GIL, THERE WERE ANY ADDITIONAL THINGS ABOUT THE  
13 POTENTIAL MARKET SHARE AND COMPARABILITY, IF YOU  
14 COULD UNPACK THAT A LITTLE BIT, BUT OTHERWISE I'LL  
15 WAIT OTHERS' COMMENTS. THANK YOU.

16 UNIDENTIFIED SPEAKER: ARE YOU REFERRING  
17 TO THE ANTIBODIES OR TO OTHER NK CELL APPROACHES?

18 DR. STEWARD: I'M REFERRING REALLY TO  
19 ANYTHING. SO THIS IS A COMBINATION PRODUCT. AND  
20 THE QUESTIONS THAT WERE RAISED BY THE REVIEWERS IS  
21 COMPARABILITY. SO HOW MUCH BETTER IS THIS IF IT IS  
22 BETTER AT ALL? AND THAT, I THINK, IS WHAT THEY WERE  
23 REQUESTING IN TERMS OF FUNDING, AND THESE TWO DO  
24 COMPARE THE (INAUDIBLE). THANK YOU.

25 DR. SAMBRANO: SO THIS IS GIL. SO THERE

1 IS DATA THAT THEY PROVIDE THAT SHOWS THAT THE NK  
2 CELL AND ANTIBODY THERAPY IS BETTER THAN THE  
3 ANTIBODY MONOTHERAPY, BUT THE NUMBER OF ANIMALS THAT  
4 WAS USED WAS RELATIVELY SMALL. THE DIFFERENCE, I  
5 THINK, FOR SOME REVIEWERS WAS NOT A LOT; BUT, AGAIN,  
6 THIS IS IN THE PRECLINICAL MODEL. SO IT WOULD BE  
7 DIFFICULT TO KNOW IN PATIENTS HOW MUCH OF A  
8 DIFFERENCE THIS WOULD MAKE. BUT I THINK THAT'S  
9 WHERE IT WAS. IT WASN'T THAT THEY DIDN'T DO THIS OR  
10 THAT IT WAS ABSENT, BUT, RATHER, THAT SOME OF THEM  
11 WEREN'T FULLY CONVINCED BY IT.

12 DR. MARTIN: LET ME JUST MAKE A COUPLE OF  
13 COMMENTS. I KNOW THIS FIELD QUITE WELL. UNUM IS A  
14 COMPANY THAT IS IN THE CLINIC WITH A MODIFIED CD16  
15 RECEPTOR, IF YOU WILL, WHICH IS THE RECEPTOR THAT'S  
16 BEING UTILIZED ON THIS NK CELL. AND THEY'VE  
17 MODIFIED IT SO THAT IT IS THE HIGH-AFFINITY  
18 RECEPTOR, WHICH IS WHAT THIS PROPOSAL IS. AND THEY  
19 ARE USING APPROVED ANTIBODIES, RITUXAN, HERCEPTIN,  
20 ETC. AND THEY'RE CLEARLY GETTING EFFICACY ABOVE AND  
21 BEYOND WHAT THE ANTIBODY WOULD DO WITH THE  
22 ENDOGENOUS NK CELLS OF THOSE PATIENTS.

23 AND IT'S BEEN SHOWN BY GENENTECH THAT, FOR  
24 INSTANCE, PATIENTS ADMINISTERED HERCEPTIN RESPOND  
25 BETTER TO THE HER2 EXPRESSING CANCER CELLS IF THEY

1 HAPPEN TO GENETICALLY HAVE NATURALLY THIS  
2 HIGH-AFFINITY RECEPTOR ON THEIR NK CELLS.

3 SO I THINK THERE'S GOOD CLINICAL EVIDENCE  
4 IN THE FIELD NOW FROM UNUM AND FROM GENENTECH THAT  
5 THE MODIFICATION OF THE RECEPTOR, AS IS PROPOSED  
6 HERE, AND KEEPING THE RECEPTOR ON THE SURFACE OF THE  
7 NK CELL IS MUCH MORE LIKELY TO BE SUCCESSFUL THAN  
8 DEPENDING UPON JUST THE ENDOGENOUS NK CELL AND THE  
9 ANTIBODIES SUCH AS RITUXIMAB OR TRASTUZUMAB FOR THE  
10 ANTIBODY ALONE THERAPY.

11 SO I THINK IT MAKES GOOD SENSE, AND IT'S  
12 SUPPORTED BY CLINICAL DATA, THAT THIS MODIFICATION  
13 AND THEN USING AN ACT OR ADOPTIVE CELL THERAPY HAS  
14 ADVANTAGES OVER JUST AN ANTIBODY AGAINST THE SAME  
15 TARGET.

16 SUPERVISOR SHEEHY: THANK YOU, DR. MARTIN.

17 DO WE HAVE OTHER COMMENTS OR QUESTIONS?  
18 DO WE HAVE ANY PUBLIC COMMENT? SO, MS. BONNEVILLE,  
19 COULD YOU CALL THE ROLL PLEASE.

20 MS. BONNEVILLE: SURE. ANNE-MARIE  
21 DULIEGE. DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MS. BONNEVILLE: STEVE JUELSGAARD.

24 DR. JUELSGAARD: YES.

25 MS. BONNEVILLE: SHERRY LANSING. DAVE

1 MARTIN.  
2 DR. MARTIN: YES.  
3 MS. BONNEVILLE: LAUREN MILLER.  
4 MS. MILLER: YES.  
5 MS. BONNEVILLE: ADRIANA PADILLA.  
6 DR. PADILLA: YES.  
7 MS. BONNEVILLE: JOE PANETTA.  
8 MR. PANETTA: YES.  
9 MS. BONNEVILLE: FRANCISCO PRIETO.  
10 DR. PRIETO: AYE.  
11 MS. BONNEVILLE: ROBERT QUINT.  
12 DR. QUINT: YES.  
13 MS. BONNEVILLE: AL ROWLETT.  
14 MR. ROWLETT: YES.  
15 MS. BONNEVILLE: JEFF SHEEHY.  
16 SUPERVISOR SHEEHY: YES.  
17 MS. BONNEVILLE: OS STEWARD.  
18 DR. STEWARD: YES.  
19 MS. BONNEVILLE: JONATHAN THOMAS.  
20 CHAIRMAN THOMAS: YES.  
21 MS. BONNEVILLE: ART TORRES.  
22 MR. TORRES: AYE.  
23 MS. BONNEVILLE: DIANE WINOKUR.  
24 MS. WINOKUR: YES.  
25 MS. BONNEVILLE: MOTION CARRIES.

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SUPERVISOR SHEEHY: THANK YOU, MS.  
BONNEVILLE. THIS CONCLUDES THE APPLICATION REVIEW  
SUBCOMMITTEE.

CHAIRMAN THOMAS: THANK YOU VERY MUCH,  
SUPERVISOR SHEEHY.

WE'RE INTO GENERAL PUBLIC COMMENT. DO WE  
HAVE ANY MEMBERS OF THE PUBLIC AT ANY SITE THAT  
WOULD LIKE TO MAKE A COMMENT AT THIS POINT? HEARING  
NONE, THAT CONCLUDES THE AGENDA FOR TODAY. THANK  
YOU, EVERYBODY. WE LOOK FORWARD TO SEEING AND/OR  
TALKING TO YOU AT OUR NEXT REGULARLY SCHEDULED  
MEETING, WHICH WILL BE MARCH 13TH. HAVE A GOOD DAY.

(THE MEETING WAS THEN CONCLUDED AT  
9:23 A.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON FEBRUARY 22, 2018, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152  
133 HENNA COURT  
SANDPOINT, IDAHO  
(208) 255-5453

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